K012333

OCT 1 7 2001

510(k) Summary

Submitter Information:

Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Contact:

Krista Oakes
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Date Prepared:

September 12, 2001

Product Name:

Common Name: SpO2 Ear Sensor (accessory to ear oximeter)
Trade Name(s): Flexi-Site SpO2 Ear Sensor

Predicate Device:

This product is substantially equivalent to the original Flexi-Site sensor, marketed under K964055, the Flexi-Site ear sensor marketed under K010718, and the Ohmeda 6051-0000-115 sensor marketed under K850494. Accuracy is equivalent to the Nellcor Dura-Y ear sensor, marketed under K944760.

Description:

The Flexi-Site SpO_2 Sensor is an electro-optical sensor that functions without skin penetration, electrical contact, or heat transfer. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The optical components are housed in a durable silicone casing. The sensor cable is terminated in a Hypertronics style connector.

Intended Use:

The Flexi-Site SpO2 Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.

Comparison to Predicate Device:

The Flexi-Site SpO_2 Sensor uses the same theory and principle of operation as the predicate device. The design is equivalent to the original Flexi-Site, with the addition of a filter and an ear clip accessory to facilitate use on the ear.

Performance Data & Conclusions:

Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. The Flexi-Site was compared to arterial blood samples analyzed on a laboratory co-oximeter. Accuracy (A_{rms}) for the Flexi-Site was 3.84% across the range of 70%-100% SaO_2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Krista Oakes
Epic Medical Equipment Services
1800 10th Street
Suite 300
Plano, TX 75074

Re: K012333
Flexi-Site SpO2 Ear Sensor
Regulation Number: 870.2710
Regulation Name: Impedance Plethysmograph
Regulatory Class: III (three)
Product Code: 73 DPZ
Dated: September 13, 2001
Received: September 17, 2001

Dear Mr. Oakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) # K012333
Device Name: Flexi-Site SpO2 Ear Sensor

Indications for Use:
The Flexi-Site SpO2 Ear Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing ≥ 30 kg.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K012333